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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,861	12/26/2001	Hai Xing Chen	99,003.1	4882

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,861

Applicant(s)

CHEN, HAI XING

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment and response to the office action filed on January 29, 2005 has been entered.
2. Claims 1, and 14 are amended. Claims 1-25 are pending. Claims 26-29 are cancelled by the amendment filed on January 29, 2004.
3. Applicants' response to the office action is fully considered and found not persuasive. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made FINAL necessitated by amendment.

New Grounds of Rejection necessitated by Amendment

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim interpretation: In the following rejection, test column is given broadest reasonable interpretation as an array and snare as a defined spot or location of capture material or target, and the term “sequential” is not defined in the instant specification and Applicants refer Figs 6-12 for the basis of the term “sequential” thus the term “sequential” is interpreted as a process having different steps and addition of reaction components at different times during the process.

Claims 1-4, 6-16, 18-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Drmanac et al. (USPN. 6,297,006).

Drmanac et al. teach a method of claims 1, 7, 14, 18, 24, for sequentially detecting multiple test materials in a test sample comprising (a) adding a test sample in to a test column (small array with multiple target sequences) having a plurality of snares (subarrays) of said snares having multiple capture materials (capture sequences to multiple individual target sequences) (see col. 3, line 64-67, col. 4, line 1-18, col. 20, line 29-59),

(c) adding a probe with a chemical label (labeled probe) that specifically binds to the said first test material (see col. 4, line 19-20, col. 20, line 64-67, col. 21, line 1-5);

(d) washing said test column to remove unbound probes (see col. 21, line 5-11);

(e) detecting the signals generated by said chemical label and determining the presence of the first test material (see col. 4, line 21-22, col. 21, line 20-28);

(f) adding a second labeled probe to attach to a second test material (see col. 4, line 23-25);

(g and h) washing and detecting signals generated by remaining probes and detecting multiple test materials (see col. 4, line 24-31).

With regard to claims 1-2, 4, 7-9, Drmanac et al. teach multiple labels (two to six probes each having a different label) with triggering solution (see col. 5, line 30-36, col. 15, line 52-65);

With regard to claims 3, 16, 25, Drmanac et al. also teach said labels are chemiluminescence labels (BAP) (see col. 15, line 38-65);

With regard to claim 6, 15, 25, Drmanac et al. teach that the test material comprises DNA (see col. 3, line 64-65);

With regard to claims 10-13, 19-23, Drmanac et al. also teach said method comprises several control DNAs which include positive and negative controls (see col. 21, line 28-35).

Thus the disclosure of Drmanac et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al. (USPN. 6,297,006) and in view of Patel et al. (USPN. 5, 945,249).

Drmanac et al. teach a method of claims 1, 7, 14, 18, 24, for sequentially detecting multiple test materials in a test sample comprising (a) adding a test sample in to a test column (small array with multiple target sequences) having a plurality of snares (subarrays) of said

snare having multiple capture materials (capture sequences to multiple individual target sequences) (see col. 3, line 64-67, col. 4, line 1-18, col. 20, line 29-59),

(c) adding a probe with a chemical label (labeled probe) that specifically binds to the said first test material (see col. 4, line 19-20, col. 20, line 64-67, col. 21, line 1-5);

(d) washing said test column to remove unbound probes (see col. 21, line 5-11);

(e) detecting the signals generated by said chemical label and determining the presence of the first test material (see col. 4, line 21-22, col. 21, line 20-28);

(f) adding a second labeled probe to attach to a second test material (see col. 4, line 23-25);

(g and h) washing and detecting signals generated by remaining probes and detecting multiple test materials (see col. 4, line 24-31).

Drmanac et al. teach multiple labels (two to six probes each having a different label) with triggering solution (see col. 5, line 30-36, col. 15, line 52-65);

Drmanac et al. also teach said labels are chemiluminescence labels (BAP) and fluorescent labels linked with NHS ester to phosphoramidite derivative oligonucleotide (see col. 15, line 38-65).

However Drmanac et al. did not teach acridinium dye as a chemical label.

Patel et al. teach laser addressable thermal imaging media comprising photothermal converting dye in association with a heat-sensitive imaging system and a photoreducing agent for said dye (see col. 3, line 20-29). Patel also teach that said dyes include cationic dyes such as polymethine dyes, acridinium dyes, cyanine dyes etc. (see col. 5, line 66-67, col. 6, line 1-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting multiple target nucleic acids using chemical labels as taught by Drmanac et al. with the step of adding photo-thermal converting dyes as acridinium dyes as taught by Patel et al. to achieve expected benefit of developing a sensitive and improved method for detecting multiple target sequences in a sample because Patel et al. taught that the use of laser addressable thermal media comprising acridinium dyes, that would give rise to multi-color images by repeated transfer of colored donors and the transfer occurs with high sensitivity and resolution and heating the transferred image for relatively short periods at temperatures in excess of about 120 C causes curing and hardening , and hence an image of enhanced durability (see col.1, line 41-58, col. 14, line 1-5). An ordinary practitioner would have been motivated to modify the method of detecting a target nucleic acids as taught by Drmanac et al. by incorporating the acridinium dye as taught by Patel et al. to develop a sensitive method for the purpose of obtaining better resolution of colored images in a relatively short exposure time and such modification of the method is considered obvious in the absence of secondary considerations.

Response to arguments

6. With reference to the rejections maintained in the previous office action under double-patenting Applicants' amendment and arguments are fully considered and are found not persuasive. Applicants argue that the instant amended claims are patentably distinct and are not obvious over the US patents 6,714,733 ('733) and 6,337,214. Applicants also argue that these patents do not disclose detecting multiple test materials on the same test snare using sequential process by adding the probes at different times, triggering and detecting the signals from the

labeled test materials at different times and direct the examiner's attention to the instant specification, Fig. 6-12. Applicants' arguments are fully considered and found not persuasive. The term "sequential" is not defined in the instant specification and the Figs. 6-12 indicate each step of the method, which is similar to the process steps in the patented claims (claims 5-7). The claims in the patent '733 disclose a test snare comprising two different nucleic acid sequences (one sequence for control and another sequence for negative control) (see claim 7), which encompasses the limitations (more than one or multiple test sequences) on the same snare of the instant claims. Likewise in the patent '214, the patented claims disclose sequential process and two different sequences on the same test snare. Further it is noted that the claims in both the patents disclose sequential process by adding probes at different times and detecting the signals at different times. Thus the instant claims are not patentably distinct and the rejections are maintained herein.

With regard to the double patenting rejection in view of Lee et al., Applicants' arguments are fully considered and found not persuasive. As discussed above the patented claims encompass the limitations of the instant claims and it is obvious to modify the method with the inclusion of a non-radioactive label for the advantage of reducing the use of hazardous radioactive labels and to increase the sensitivity of the assay. Thus the rejections are maintained herein.

7. With reference to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found persuasive and the rejection is withdrawn in view of the amendment and new grounds of rejections.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER

